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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,652	03/13/2001	D. Laksen Sirimanne	412692000401	4202

25226 7590 05/21/2003

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EXAMINER

LIN, JEYUHU

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 05/21/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/805,652

Applicant(s)

SIRIMANNE ET AL.

Examiner

Jeoyuh Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 13, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24, 27 and 35 is/are rejected.
- 7) ☒ Claim(s) 22, 23, 25, 26, 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

-Claims 1-10, 14-18, 24, 27, 28, 32, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Sing et al. (6,183,497 B1).

Sing teaches an absorbable sponge implantable into the body, comprising the following:

- Resilient bioabsorbable polymeric filler body, which could be polymeric gelatin (Column 3, lines 50-55), in the form of a sponge, (Column 3, lines 8-13) as claims 1 and 18 teach
- Detectable non-absorbable or bioabsorbable marker, in the form of radiopaque powder (Column 3, lines 38-40) affixed to filler body, wherein

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marker has a form distinguishing it from tissue calcification, because of their unique chemical make-up. The marker could also be detectable by ultrasound, making it echogenic.

-Ability to deliver a variety of therapeutic agents, including thrombin, a hemostatic agent, or radioactive material (Column 3, line 13), as claim 17 teaches.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

-Claims 19-21 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing.

Sing fails to teach having a particular shape for the marker. However, it is an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to select a particular shape for the marker, or make it hollow, in order to distinguish it from the surrounding body, and so that it may maximize its fit in the body without injuring the surround tissue, and so that one may put more therapeutic agents in the marker.

-Claims 11-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Sing, as applied to claim 1 above, and further in view of Burbank. (US 6,151,034)

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Sing meets all the claims except that it fails to teach a mammographic marker and filler body that's palpable. However, it does hint at possible adaptation of the device to various kinds of biopsy procedures. Burbank teaches a biopsy marker comprising the injection of a marker into a breast, and in which the marker would be palpable. (Column 4, lines 30-35) It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt Burbank's teachings to Sing's device such that the application of the device can be extended to breast biopsy.

Allowable Subject Matter

3. Claims 22, 23, 25, 26, 33, and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Jensen et al. (US 6,181,960 B1) Teaches a biopsy marker device comprising a metallic metal barb. However, it fails to teach locating the marker inside a filler

-Foerster et al. (US 6,228,055B1) teaches a biopsy-marking device comprising wire, suture, barb, or woven structures for the marker. However, it fails to teach having a filler embodying the marker.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on m-f, 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JYL

JYL
May 13, 2003



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700